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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,877

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Robert C. Downs

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05/02/2008

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NOVARTIS RESEARCH FOUNDATION
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EXAMINER

SINES, BRIAN J

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

05/02/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
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Office Action Summary	Application No. 10/071,877	Applicant(s) DOWNS ET AL.	
	Examiner Brian J. Sines	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-23, 30-43 and 45-71 is/are pending in the application.
- 4a) Of the above claim(s) 59-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-23, 30-43 and 45-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the amended claims have been considered but are moot in view of the new ground(s) of rejection. The previous prior art rejection has been modified in view of applicant's arguments and amendments. The objection to the drawings has been withdrawn in view of applicant's arguments and amendments. The previous rejection of the pending claims under 35 U.S.C. 112, second paragraph, have been withdrawn in view of applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1 – 9, 11 – 21, 23, 30 – 38, 41 – 43, 45 – 49, 53, 54 and 56 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (U.S. Pat. No. 4,708,940) (“Yoshida”) in view of Roginski et al. (U.S. Pat. No. 4,927,545) (“Roginski”) and Jovanovich et

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al. (U.S. Pat. No. 6,423,536 B1) (“Jovanovich”), and further in view of Pang et al. (U.S Pat. No. 6,060,022 A) (“Pang”).

Regarding claims 1, 9, 14, 16, 19, 20, 21, 32, 48 and 58, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe or tube 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions 103a (see col. 2, line 28 – col. 7, line 63; figure 6). As shown in figure 6, the sample receiving regions 103a can be arranged in a non-vertical position during operation.

Yoshida does teach the use of a transport mechanism (e.g., driving device 13 & arm 35) configured to move two processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within one of the sample receiving regions 103a at a time (see col. 2, line 28 – col. 7, line 63; figure 6).

Yoshida does not specifically teach the incorporation of a transport mechanism that is configured to move one or more processing components proximal to or within each of two or more sample receiving regions comprising a plurality of sample-holding vessels at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor.

Jovanovich does teach an automated centrifuge system comprising: a microplate bucket (43); centrifuge (42); and a transport mechanism (e.g., automated robot 102 comprising transfer head 104 containing capillary cassette 15) that is configured to move one or more processing components (capillary tubes 12) proximal to or within each of two or more sample vessels

(wells 36a of multiwell plate 36) at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor (41) (see figures 1, 5A and 5B; col. 9, line 56 – col. 11, line 17).

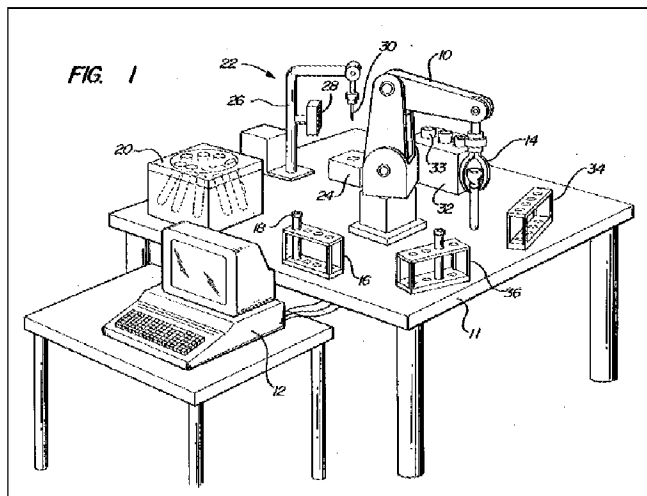
As shown by Jovanovich, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a robotic transport mechanism for moving one or more processing components, i.e., sample fluid transfer tubes, proximal to or within two or more sample vessels, e.g., wells of a multi-well plate, at the same time and when the sample vessels are present within the rotor. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the applicant is advised that the United States Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the U.S. Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements according to known methods is likely to be obvious when it

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does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the transport mechanism as claimed with the disclosed centrifuge device to facilitate effective sample processing.

Yoshida does not specifically teach that the sample receiving regions are arranged in a fixed non-vertical configuration.

However, the use of fixed non-vertical or angled sample receiving regions for holding samples in centrifuge devices during operation is notoriously well known in the art (see MPEP § 2144.03). For example, Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29 – col. 4, line 65; figure 1).



As shown in figure 1, the centrifuge (20) comprises a single non-vertical fixed-angle cluster comprising receiving regions for test tubes. The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972). Furthermore, the

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combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated centrifuge apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robotic arm as claimed with the disclosed apparatus.

Regarding claims 2 and 3, Yoshida teaches the incorporation of an optical rotor position sensor (e.g., photocoupler 6) (see col. 3, lines 29 – 59).

Regarding claim 4, Yoshida teaches the incorporation of a centrifuge chamber (e.g, the container comprising centrifugal separator 1) and a rotor cover (lid 9) (see figures 2 & 3; col. 3, lines 29 – 59).

Regarding claims 5 and 35, Yoshida teaches the incorporation of a reference index (e.g., disk 31 & pot detector 127), which facilitates rotor positioning (see col. 3, lines 29 – 48; figures 2 & 6).

Regarding claims 6 – 8, Yoshida teaches the incorporation of a motor (driving device 5) (see col. 3, lines 29 – 48).

Regarding claims 30, 31, 33, 34, 36 – 38, 42 and 43, Yoshida teaches the incorporation of a controller (150) comprising a microcomputer for operating the disclosed apparatus (see col. 7,

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lines 9 – 16). Therefore, it would have been obvious to a person of ordinary skill in the art to provide appropriate software for monitoring and controlling the automated centrifuge system.

Regarding claims 49, 53 and 54, Yoshida teaches the incorporation of an analyzing section (200) comprising a specimen collector (e.g., flow cell 224), which collects a specimen for analysis (see col. 5, line 35 – col. 63; figure 1).

Regarding claim 55, it would have been obvious to a person of ordinary skill in the art to incorporate a fraction dispensing element, such as tubing positioned within a test tube, for the specimen collection. The use of tubing is well known in the art to facilitate sample fluid transfer (see MPEP § 2144.03).

Regarding claim 46, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3).

Regarding claim 47, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3). Yoshida does not indicate the incorporation of two bins, tubes or containers and a runoff ramp. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to incorporate two containers for rinsing. The use of ramps for directing fluid flow are well known in the art (see MPEP 2144.03). Therefore, it would have been obvious to incorporate a runoff ramp with the disclosed apparatus for facilitating runoff fluid flow.

Regarding claim 56, the incorporation of second transport mechanism with the disclosed apparatus would have been obvious to a person of ordinary skill in the art. The Courts have held

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that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

Regarding claim 57, Yoshida teaches an apparatus comprising: sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); various sample processing components (e.g., sample take-out pipe 12 & sensing electrode 17); various hoses (e.g., sample transfer pipe 201), which inherently have tips or ends; various pumps (206, 213, 219 & 231); a fluid source (e.g., reagent reservoirs 209 – 212); a specimen collector (e.g., flow cell 224); various switches or valves (e.g., switching valves 240, 250, movable valve 40, slide valve 202); a waste dump (e.g., washing tube 16) (see col. 3, line 1 - col. 7, line 64; figures 1 – 3, 6 & 7). The Court has recognized that an artisan is presumed to have skill, rather than lack of skill. See *In re Sovish*, 226 USPQ 771 (Fed. Cir. 1985). It would have been obvious to a person of ordinary skill in the art to provide appropriate tubing or hose connections, pump connections, etc., between the various system components as claimed to facilitate effective device operation.

With respect to claims 1, 11 – 13, 15, 17, 18 and 23, neither Yoshida nor Jovanovich specifically teach the incorporation of a sample cluster configuration comprising a plurality of sample-holding vessels. As shown by Pang, the use of a clustered sample holding configuration in addition to a robotic mechanism with automated centrifuge systems is well known in the art (see, e.g., col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Pang teaches that each cluster or bucket 1200 holds a plurality of containers 12 or test tubes 102 (see col. 11, lines 25 – 54). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration including a robotic transport

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mechanism with an automated centrifuge system (see MPEP § 2143.02). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system.

Regarding claim 41, the above cited prior art does not specifically teach the incorporation of a recognition means with the disclosed apparatus. Roginski teaches the incorporation of a recognition means (e.g., barcode reader 28, 78 & optical sensor 24) (see col. 1, line 29 - col. 8, line 36). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a recognition means with the centrifuge system for facilitating effective sample processing.

Regarding claim 45, the incorporation of a second rotor as claimed would have been obvious to a person of ordinary skill in the art. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the above cited prior art and further in view of Alam et al. (U.S Pat. No. 5,792,050 A) ("Alam").

Regarding claim 22, the aforementioned cited prior art does not specifically teach the incorporation of a sonication apparatus. Although Yoshida does teach the incorporation of a fluid

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transfer tube (e.g., sample transfer pipe 201 & sample take-out pipe 12) (see col. 3, line 29 – col. 6, line 57; figures 2 & 3). Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Alam, the use of sonication probes in assisting in the biochemical analysis of blood samples is well known in the art (see col. 6, lines 55 – 65). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of utilizing a sonication device in facilitating the analysis of blood samples. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the Courts have held that to provide a mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the ambit of a person of ordinary skill in the art. See *In re Venner*, 120 USPQ 192 (CCPA 1958). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of sonication devices and fluid transfer tubes as claimed with the disclosed apparatus.

3. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above cited prior art, and further in view of Taylor (U.S. Pat. No. 4,822,331) (“Taylor”).

Regarding claims 39 and 40, the aforementioned cited prior art does not specifically teach the incorporation of operator safety members. As shown by Taylor, the incorporation of safety mechanisms with laboratory equipment comprising a centrifuge is well known in the art. Taylor does teach the incorporation of a safety member (e.g., motor 103, clutch 160, stop sleeve 171, relay 154, contact 151, run switch 59 & stop switch 185) with a centrifuge apparatus (see col. 8, line 3 – col. 11, line 20). Thus, as evidenced by Taylor, a person of ordinary skill in the art

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would accordingly have had a reasonable expectation for success in incorporating the use of a safety mechanism with the centrifuge system. Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007).

Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a safety mechanism as claimed with the disclosed apparatus, in order to provide safe operation.

4. Claims 50 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the aforementioned cited prior art, and further in view of Feldman (U.S Pat. No. 5,445,958 A) (“Feldman”).

Regarding claims 50 – 52, the aforementioned cited prior art does teach the incorporation of a sample analyzing section (200) (see col. 5, lines 35 – 46). In addition, the above cited prior art does not specifically teach the incorporation of a sample purification apparatus comprising a nickel-chelate resin. Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Feldman, the use of liquid column chromatography utilizing a nickel-chelate resin, such as a chelating sepharose resin comprising immobilized iminodiacetic acid groups, in the separation and analysis of blood plasma samples is well known in the art (see col. 4, line 29 – col. 8, line 55). In addition, the Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). Therefore, it

would have been obvious to a person of ordinary skill in the art to incorporate such a separation component as claimed with the disclosed apparatus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
Art Unit 1797

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